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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JIANG, DONG	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,511	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *8-11, 13-30 and 32-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,12 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,4,14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election without traverse of Group I invention in Paper No. 16, filed on 30 January 2003 is acknowledged. Applicant's species election without traverse of SEQ ID NO:51 and 53 in Paper No. 16 is acknowledged. Additionally, applicants point out that SEQ ID NO:51 is a cDNA sequence that includes SEQ ID NO:52 in its entirety, and request for the consideration of the claims with respect to the sequences of both SEQ ID NO:51 and 52. This request is persuasive, and requirement for the species restriction between SEQ ID NO:51 and 52 is withdrawn.

Currently claims 1-43 are pending, and claims 1-7, 12 and 31 are under consideration. Accordingly, claims 8-11, 13-30 and 32-43, as non-elected inventions, are withdrawn from consideration.

The references listed on the PTO-1449 in papers No. 3 and 14 are not present in the current application file. In response to this Office Action only, applicants may submit another set of the same references, and the Examiner will consider them as though they were submitted with IDS in papers No. 3 and 14 (the US patents have been considered).

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

The specification is objected to for leaving ATCC accession number and deposit date blank at page 139, lines 26 and 27, and page 140, lines 1 and 2.

Claims 1, 2 and 12 are objected to for encompassing a non-elected subject matter, SEQ ID NOs other than SEQ ID NO:51-53. The applicant is required to amend the claims to read only upon the elected invention.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 12 and 31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific, or well-established utility.

Claims 1-7, 12 and 31 are directed to isolated nucleic acid sequences of SEQ ID NO:51 and 52 encoding polypeptide of SEQ ID NO:53, fragments thereof, vectors containing same, host cells thereof, and a method of recombinantly producing the encoded polypeptide, which is designated TANGO405.

The specification discloses the polynucleotide sequences with SEQ ID NO: 51 and 52, which encode a human TANGO405 polypeptide having SEQ ID NO:53. Based on sequence homology, the specification asserts that human TANGO405 is the human ortholog of murine dectin-2 (page 53, lines 23-24). Further, the specification asserts that as murine dectin-2 has been shown to be involved in activation of naive T cells and in inflammation and non-T cell mediated immune responses, thus, human TANGO405 is also involved in activating or inhibiting one or more types of lymphocytes, thereby modulating immune responses, inflammatory responses and other components of the immune response (page 56, the last paragraph), and that as cDNA corresponding to TANGO405 occurs in a human mixed lymphocyte reaction cDNA library, it is evident that TANGO405 protein is involved in one or more biological processes occurring in these tissues, such as modulating growth, proliferation, or differentiation of the cells, and modulating the structure of extracellular matrix (page 56, lines 9-20).

The asserted utilities discussed above are not considered substantial because the assertion is based mainly on the sequence homology of the human TANGO405 with murine dectin-2, and the tissue origin. Such prediction based upon sequence similarity of known proteins cannot be accepted in the absence of supporting evidence, because it is well known that many proteins belong to a same family, share a high degree of sequence similarity, yet have diverse, and sometimes even opposite biological activities and functions. For example, in the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-

9026) disclose that OP-1, a member of the TGF-family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF- family members BMP-2 and TGF-1 had no effect on metanephrogenesis under identical conditions (p. 9023, paragraph bridging columns 1-2). Additionally, Skolnick et al. (Trends in Biotechnology, 2000) teaches that because proteins can have similar structures but different functions, determining the structure of a protein may not necessarily reveal its function (see entire article, especially Box 2). Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologues must have different molecular and cellular functions. Therefore, in the absence of any actual experimental confirmation of any of biological properties, the skilled artisan would not accept the asserted activity as being substantial.

In addition, the specification does not specify how the human TANGO405 is involved in said activities, and what exactly role the human TANGO405 plays in those events. A substantial utility, by definition, is a utility that defines "real world" use, and a utility that requires or constitutes carrying our further research to identify or reasonably confirm a "real world" context of use is not a substantial utility. In the instant case, the sequence homology of the human TANGO405 to murine dectin-2, at the most, is an interesting invitation for further research and experimentation to confirm the exact role and functional property of the protein, and its "real world" use is yet to be found. Upon further research, a substantial utility might be found for the claimed isolated nucleic acid and/or the protein encoded thereby. These further research and experimentation, however, is part of the act of invention, and until it has been undertaken, the claimed invention is not considered substantial.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the

intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. ... a patent is not a hunting license. ... [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to polynucleotides encoding proteins of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that the claimed nucleic acids encoding TANGO405 were, as of the filing date, useful for the disclosed purposes. Until some actual and specific biological significance can be attributed to the polynucleotides or the polypeptide identified in the specification as TANGO405, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility and the claimed invention is incomplete as of the filing date.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 12 and 31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the specification taught how to use human TANGO405, enablement would not be commensurate in scope with claim 1, and the dependent claims 3-7 and 12, which reads on nucleic acids of SEQ ID NO:51 and 52, nucleic acids encoding SEQ ID NO:53 (claim

1, part c), or fragments thereof (claim 1, parts b) and d), for example), and variants thereof (% variants and allelic variants, claim 1, parts a) and f), for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with the claims. The specification discloses merely one human gene and its cDNA with SEQ ID NO: 51 and 52, respectively, which encodes a polypeptide of SEQ ID NO:53, or TANGO405, and provides neither guidance, nor working example to teach how to make any of variants of TANGO405. The specification indicates that a fragment of a nucleic acid sequence can be used as a probe, a primer, or to encode a biological active portion of a polypeptide of the invention. However, the specification does not teach that as a probe, whether these nucleic acid fragments are specific and hybridize *only* to TANGO405 polynucleotide, or they may represent parts of conservative regions and hybridize to other members of the family. Further, the specification does not define any domain or region in TANGO405 as a "biological active portion", nor, in fact, has any specific biological activity been disclosed for TANGO405. Without knowing what the biological activity is, it would require undue experimentation to make a fragment conserving such. Additionally, the skilled artisan would not know how to use the fragments which neither is specific to TANGO405, nor encodes a "biological active portion".

Claims 1, 2 and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 2 and 12 recite a deposit of a DNA clone of SEQ ID NO:51 or 52. However, the specification fails to provide the deposit statement indicating the deposit material will be readily available to the public without restriction upon issuance of the patent. Such statement would satisfy the enablement requirement of 35 U.S.C. 112. For each deposit made pursuant to these regulations, the specification shall contain: (1) The accession number for the deposit; (2) The date of the deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) The name and address of the depository. [See MPEP 2404-2410.02]

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

(a) that the deposit has been made under the terms of the Budapest Treaty; **and**

(b) that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent,

would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then the requirements may be satisfied by an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or by a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and establishing that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 C.F.R. 1.807 is provided; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination, or loss of capability to function described in the manner in the specification.

In either case, the identifying information set forth in 37 C.F.R. 1.809(d) should be added to the specification if it is not already present. For deposits made with the ATCC, note that effective 23 March 1988 the depository's address is:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

See 37 C.F.R. 1.803-1.809 for additional explanation of these requirements.

Claims 1 and 12 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The claim limitation of claim 1, part f), and claim 12, part c) is directed to a naturally occurring allelic variant of a polypeptide encoded by SEQ ID NO: 51 or 52. The specification discloses SEQ ID NO: 51 or 52, and the putative polypeptide encoded thereby (SEQ ID NO:53). No other variants or species of SEQ ID NO:53 meeting the limitations of these claims were ever identified or particularly described. The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, the claim directed to a naturally occurring allelic variant of a polypeptide encoded by SEQ ID NO:1 was found to be unpatentable due to lack of written description for that broad class.

Therefore, only the isolated polypeptide encoded by SEQ ID NO:51 or 52, but not the full breadth of the claim, meets the written description provision of 35 U.S.C. §112, first paragraph. This is particularly important in absence of a specific known activity. Applicant is

reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 12 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is unclear what it is meant by "comprising the amino acid sequence of ... *and* the amino acid sequence encoded by ..." in parts c)-f). It does not appear from the specification that the nucleic acid or the polypeptide comprises sequences from multiple SEQ ID NOs or ATCC clones is intended. Claims 2 and 12 are similarly indefinite.

Claims 1, 2 and 12 are further indefinite to for leaving ATCC accession number blank. As such, the metes and bounds of the claims cannot be determined.

Claim 4 is indefinite because it is unclear what is the structural relationship of the heterologous polypeptide with said polypeptide.

The remaining claims are rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3-7 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Ariizuni et al, US 6,046,158.

Ariizuni discloses a nucleic acid, SEQ ID NO:3, which encodes a murine dectin-2 protein, and comprises nucleotides 187-212 of SEQ ID NO:52 of the present invention with 100% identity, and nucleotides encoding amino acids 60-71 of SEQ ID NO:53 of the present invention with 100% identity (see appended computer printout of sequence search result). The cited sequence, therefore, anticipates claim 1 as being a nucleic acid molecule comprising a nucleotide sequence identical to at least 15 consecutive nucleotide residues of SEQ ID NO:52 (as claim 1, part b), for example), and a nucleic acid molecule encoding a fragment of at least 10 consecutive amino acid residues of SEQ ID NO:53 (as claim 1, part d), for example). Additionally, Ariizuni teaches an expression vector comprising said nucleic acid (column 6, line 31 to column 7, line 65), a host cell thereof, wherein the host cell is a mammalian cell, or a non-human mammalian cell, such as CHO cell (column 7, line 65 to column 8, line 37), and a recombinant method for producing said polypeptide (Example 5). The reference, therefore, anticipates claims 3, 5-7 and 12. Furthermore, Ariizuni teaches a nucleic acid encoding said polypeptide fused with a heterologous polypeptide such as a His tag (column 5, lines 19-32), and thus, the reference also anticipates claim 4.

Claims 1, 3-7 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Ariizuni et al, WO 98/28332 (cited by applicants in PTO-1449) for the same reasons above as the pertinent issues are identical.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0405.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
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AU1646
3/10/03